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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,665	06/12/2001	Douglas R. Daum	279.358US1	4223

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EXAMINER	
OROPEZA, FRANCES P	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,665	Applicant(s) DAUM, DOUGLAS R.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The Applicant's comments have been fully considered and are convincing, hence the rejections of record are withdrawn and a new grounds of rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 1, 10, 11, 13-17, 23, 25-31, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheldon et al. (US 6044297).

Sheldon et al. disclose an implantable medical device and teach detecting a condition, patient position/ activity, correlative to hypotension. The pacing rate is adjusted based on the metabolic need as measured by an array of accelerometers (col. 1 @ 6-16; col. 7 @ 23-36; col. 9 @ 10-13; col. 22 @ 4-9).

As to claim 11, monitoring the blood pressure and position enables correlation both to a hypertension associated with a change in posture and to a hypertension not associated with a change in posture (col. 7 @ 23-36; col. 9 @ 10-13).

As to claims 14-16 and 27-30, the rate responsive factor is stepped (col. 7 @ 31-34; col. 11 @ 63 – col. 12 @ 9). US 5354317 to Alt, incorporated by reference (col. 2 @ 51-53; col. 3 @ 7-17), discloses variable rate pacing to provide electrical output signals uniquely responsive to pre-selected positions, including gradual rate changes (Alt - abstract).

As to claims 9 and 26, activity levels associated with two timers are used to reflect activity, the activity being correlated with blood pressure to determined pacing (col. 11 @ 20 – col. 12 @ 9).

Claim Rejections - 35 USC § 103

3. Claims 2-9, 12, 18-22, 24, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Combs et al. (US 5957861). Sheldon et al. teach hypotension can be associated with fluid shifts and suggest an indirect measurement of fluid level changes, sleep cycle and position change, to monitor the need for an adjusted pacing rate. Combs et al. teaches a more direct and exact means to measurement of fluid changes using respiratory rate and/or impedance. As discussed in paragraph 2 of this action, Sheldon et al. discloses the claimed invention except for:

- detecting thoracic impedance (claims 2, 12 and 32) associated with fluid shift from the thorax (claim 3) by detecting an increase in the baseline (claim 4) (claim 18),
- filtering (claim 20) with the impedance frequency value being 0.01 to 0.5 Hz (claims 5 and 21), or approximately 0.1 Hz (claims 6 and 22),
- attenuating a high frequency component of the thoracic impedance (claim 7),
- detecting a breathing signal (claims 8 and 35), and
- electrodes associated with the thorax (claim 19).

Combs et al. disclose a device (10) with an impedance monitor for discerning edema through the evaluation of respiratory rate and/or impedance, and teach the following elements combinable, for the reasons noted, to modify the implantable medical device as taught by Sheldon et al.:

As to detecting thoracic impedance (claims 2, 12 and 32) associated with fluid shift from the thorax (claim 3) by detecting an increase in the baseline (claim 4) (claim 18) - A thoracic impedance signal is detected using a thoracic signal detection module (17) (figure 1; col. 3 @ 16-25; col. 4 @ 33-34), detecting impedance associated with a fluid shift away form the thorax. Transthoracic impedance measurements give a good indication of the level of edema (abnormal accumulation of fluid) in patients (col. 1 @ 11-16). Edema provides a sign of failing heart circulation (col. 1 @ 28-30), and is manifest in pulmonary edema of increased water in the lungs (col. 2 @ 38-42). Edema is indicative of patient health and the need for modified therapy (col. 2 @ 12-16 and 30-36; col. 3 @ 13-15; col. 4 @ 1-4; col. 5 @ 56-61; col. 9 @ 48-59; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 52- 58; col. 15 @ 24-27). Therapy is provided based at least in part of the baseline portion of the detected thoracic impedance (col. 4 @ 1-4; col. 7 @ 13-33; col. 11 @ 48-53). Impedance is monitored to indicate health status and the need for therapy modification in order to automatically provide treatment responsive to the onset of edema (col. 4 @ 1-4).

As to filtering (claim 20) and the impedance frequency value being 0.01 to 0.5 Hz (claims 5 and 21), or approximately 0.1 Hz (claims 6 and 22), the filter, read as the averager/ low pass filter, uses the 0.05Hz to 0.5 Hz frequency range to establish optimize signal quality enabling automatic treatment at the onset of edema (col. 4 @ 1-4; col. 7 @ 6-15).

As to attenuating a high frequency component of the thoracic impedance (claim 7), a high frequency component of the thoracic impedance signal is attenuated (col. 6 @ 58 – col. 7 @ 33) to reduce unwanted data/ noise from the signal so an accurate diagnosis and appropriate treatment can be automatically provided at the onset of edema (col. 4 @ 1-4).

As to detecting a breathing signal (claims 8 and 35), breathing is detected and therapy provided based exclusively or in part on the detected breathing (col. 5 @ 36-45; col. 12 @ 1-16; col. 13 @ 20-26; col. 13 @ 59-64) to provide multiple data points to confirm the diagnosis so appropriate treatment can be automatically provided at the onset of edema (col. 4 @ 1-4).

As to electrodes associated with the thorax (claim 19), two electrodes enable the signal to be measured (col. 3 @ 23-25) so effective treatment can be automatically provided at the onset of edema (col. 4 @ 1-4).

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/8/03

Angela D. Sykes

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